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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,650

07/02/2003

Michael R. Hale

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/613,650	HALE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9, 10, 12-17 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 9, 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 27-29 and 31 is/are rejected.
- 7) ☒ Claim(s) 1-7, 10, 12, 13, 15, 17, 23, 25, 26 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. According to paper filed on Nov. 27, 2006, the applicants have canceled claims 8, 11 and 18-22; amended claims 1-7, 10, 17, 23, 26 and 27 and furthermore, have added new claims 28-31.
2. Claims 1-7, 9, 10, 12-17 and 23-31 are pending in the application. Claims 9, 14 and 16 remain withdrawn as being directed to non-elected subject matter.

### ***Response to Arguments***

3. Applicant's arguments filed on Nov. 27, 2006 have been fully considered but they are not persuasive regarding enablement rejection of claims 24, 27-29 and 31 as well as regarding objection for containing non-elected subject matter. In regard to enablement rejection, the examiner does not agree with the applicant's arguments that no undue experimentation is necessary for predicting efficacy of combination treatment. As stated clearly in the last office action, there is lot of unpredictability for the outcome of combination treatment. The applicants have not provided any experimental evidence for showing advantage of the combination treatment such as synergistic effect, potentiation of therapeutic effect, reduced toxicity etc. of the instant compounds with any other antiviral agents using MT4 cells. Their arguments are simply based on speculation based on well documented experimental data showing advantage of certain combinations of antiviral agents having totally different mechanism of action. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of various variables and therefore, it would require undue experimentation to demonstrate advantages of combination treatment of instant compounds with

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hundreds of thousands of other antiviral compounds in MT4 cells and hence their utility for treating HIV virus infection.

In regard to objection for containing non-elected subject matter, the examiner does not agree with the applicant's arguments that the instant claims are directed to elected subject matter. According to the compounds in table 1 on page 26 directed to the elected group, variable D represents a benzyl group only. However, in the instant claims, variable D can be C1-C6 alkyl optionally substituted with Q which can represent 3-5 and 7-membered saturated, partially saturated carbocyclic rings as well as 3-7-membered heterocyclic rings. Also, in claim 17, compounds 363 and 364 do not read on the elected group due to value of variable R' group.

### ***Conclusion***

4. Rejection of claims 24 and 27 as well as of newly submitted claims 28, 29 and 31 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

5. Objection of claims 1-7, 10, 12, 13, 15, 17, 23, 25, 26 and 30 for containing non-elected subject matter is maintained for the reasons of record.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

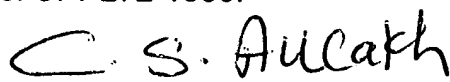
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625